

*ELECTRONIC FILING*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.	: 7,241,304 B2	Confirmation No.	: 9956
Inventor	: William J. Boyle et al.		
Issued	: July 10, 2007		
Art Unit	: 3734		
Examiner	: Victor X. Nguyen		
Title	: FLEXIBLE AND CONFORMABLE EMBOLIC FILTERING DEVICES		
Docket No.:	: ACSES 57046 (2898P)		
Customer No.	: 24201		

REQUEST FOR CERTIFICATE OF CORRECTION

Certificate of Correction Department  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

The above-identified patent has been found to have the errors set forth in the enclosed Certificate of Correction. It is requested that this Certificate of Correction be issued and returned to us. Since these errors occurred in the final printing phase of the patent and in the final application, a credit card payment to cover the required fees is enclosed. The Commissioner is authorized to charge any additional fees to our Deposit Account No. 06-2425.

The errors are verifiable in the patent application file as follows:

## **ERROR**

Title page, OTHER PUBLICATIONS, delete "Dilatation of the Carotid Artery" and insert --Dilatation of the Carotid Artery--.

Page 4, U.S. PATENT DOCUMENTS, delete "7,097,834 B1 8/2006 Boyle et al." and insert --7,097,440 B2 8/2006 Papp et al.--.

Column 4, line 36, delete "in a outward" and insert --in an outward--.

Column 4, line 64, delete "to deployed" and insert --to be deployed--.

Column 8, line 57, continue on with "In this manner" (not a new paragraph).

Column 9, line 66, delete "fill-length" and insert --full-length--.

Column 12, line 9, delete "possible" and insert --possibly--.

Column 13, line 24, continue on with "This process of forming" (not a new paragraph).

Column 14, line 13, delete "polyolifin" and insert --polyolefin--.

Column 15, line 30, delete "claim 7" and insert --claim 10--.

Column 16, line 50, delete "an collapsed" and insert --a collapsed--.

## **VERIFICATION**

Applicant error.

PTO printing error and Applicant error. Information Disclosure Statement dated October 13, 2006. See attachment.

Applicant error.

Applicant error.

Specification dated December 21, 2001, page 15, line 1. See attachment.

Specification dated December 21, 2001, page 16, line 27. See attachment.

Applicant error.

Specification dated December 21, 2001, page 24, line 1. See attachment.

Applicant error.

Amendment mailed October 10, 2006, page 9, previously numbered claim 61. See attachment.

Applicant error.

These errors occurred in good faith and correction thereof does not involve such changes in the patent as would constitute new matter or would require re-examination.

It is requested that a Certificate of Correction be issued and returned to us.

This document is being transmitted electronically.

Date: September 21, 2007

Respectfully submitted,

FULWIDER PATTON LLP

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196631.1

Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet  of 

## Complete if Known

Application Number	10/027,915
Filing Date	December 21, 2001
First Named Inventor	William J. Boyle
Art Unit	3734
Examiner Name	Vi X. Nguyen
Attorney Docket Number	ACSES-57406 (2898P)

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number	Kind Code* (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
1/1	409.	6,991,641		01-31-2006	Diaz et al.	
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In this manner, the shape of the hinge regions creates a natural hinge that helps to actuate the expandable cage between the unexpanded and expanded positions. As can be best seen in FIG. 2, the U-shaped bending regions 54 and 56 are positioned directly opposite the U-shaped portion of the distal bending regions 58 and 60. The positioning of the direction of the U portion also enhances the ability of the circumferential member to bend. These circumferential members 46 and 48, while being quite bendable, nevertheless maintain sufficient radial strength to remain in the deployed position to hold the filter element 26 open in the body vessel for collecting embolic particles which may be entrained in the body fluid.

The shape of the bending regions are shown as substantially U-shaped portions, however, any one of a number of different shapes could also be utilized to create a natural bending point on the circumferential member. For example, a V-shaped region could also be formed and would function similarly to a U-shaped portion to facilitate the collapse and expansion of the circumferential member as needed. Alternative shapes and sizes of the bending regions also could be utilized without departing from the spirit and scope of the invention. Although four bending regions are shown on each circumferential member, it should be appreciated that the number of different bending regions could be increased or decreased as needed. For example, it is possible to utilize only two bending regions, as is shown in the embodiment of the expandable cage of FIG. 6, in order to facilitate bending. Additional bending regions also could be utilized in the event that additional proximal or distal struts are used to form the expandable cage. Moreover, different sizes, shapes and location of the bending regions can be utilized on any circumferential member.

The expandable cage 24 of FIGS. 1 and 2 is shown rotatably mounted to the distal end of the guide wire 28 to allow the entire filtering assembly 22 to remain stationary once deployed in the body vessel. This feature prevents the filtering assembly from rotating in the event that the proximal end of the guide wire is

accidentally rotated by the physician during use. As a result, the possibility that the deployed filtering assembly 22 could be rotated to cause trauma to the wall of the vessel is minimized. Referring specifically to FIGS. 1 and 2, the first end 64 of the proximal struts 42 and 44 are attached to the collar 65 which is rotatably mounted on the guide wire 28 between a pair of stop fittings 72 and 74. The stop fittings 72 and 74 allow the expandable cage 24 to spin on the guide wire but restricts the longitudinal movement of the cage on the guide wire. This particular mechanism is but one way to rotatably mount the expandable cage 24 to the guide wire 28.

The expandable cage is shown in FIGS. 1 and 2 does not include a segment of guide wire which would otherwise extend through the expandable cage 24 to the distal end where the coil tip 76 extends through the obturator 32. In this manner, the elimination of this short segment of guide wire through the expandable cage 24 may help collapse the filter assembly 22 to a smaller delivery profile. The lack of the guide wire segment also may help to increase the flexibility and bendability of the filtering assembly 22 somewhat as it is being delivered through the patient's vasculature.

Referring now to FIG. 5, an alternative version of the embolic filtering device 20 is shown as it is rotatably mounted onto a guide wire 28. In FIG. 5, the filter element has been removed to better show the portion of the guide wire which extends through the expandable cage to the coil tip of the guide wire. In this particular embodiment, a short segment of guide wire 78 is present and extends through the expandable cage 24 and extends through the obturator 32. This particular embodiment of the embolic filtering device functions in the same fashion as the filter device shown and described in FIGS. 1-4. However, a full-length guide wire is utilized in conjunction with this particular embodiment. While this particular embodiment of the filtering device may not be collapsed to a smaller profile as the one shown in FIGS. 1 and 2, nevertheless it has the advantage of a full-length guide wire which allows the physician to manipulate the proximal end of the guide wire in

upper plateau strength is about a minimum of 60,000 psi with an ultimate tensile strength of a minimum of about 155,000 psi. The permanent set (after applying 8% strain and unloading), is less than approximately 0.5%. The breaking elongation is a minimum of 10%. It should be appreciated that other compositions of nickel-titanium can be utilized, as can other self-expanding alloys, to obtain the same features of a self-expanding cage made in accordance with the present invention.

In one example, the cage of the present invention can be laser cut from a tube of nickel-titanium (Nitinol) whose transformation temperature is below body temperature. After the strut pattern is cut into the hypotube, the tubing is expanded and heat treated to be stable at the desired final diameter. The heat treatment also controls the transformation temperature of the cage such that it is super elastic at body temperature. The transformation temperature is at or below body temperature so that the cage is superelastic at body temperature. The cage is usually implanted into the target vessel which is smaller than the diameter of the cage in the expanded position so that the struts of the cage apply a force to the vessel wall to maintain the cage in its expanded position. It should be appreciated that the cage can be made from either superelastic, stress-induced martensite NiTi or shape-memory NiTi.

The cage could also be manufactured by laser cutting a large diameter tubing of nickel-titanium which would create the cage in its expanded position.

Thereafter, the formed cage could be placed in its unexpanded position by backloading the cage into a restraining sheath which will keep the device in the unexpanded position until it is ready for use. If the cage is formed in this manner, there would be no need to heat treat the tubing to achieve the final desired diameter. This process of forming the cage could be implemented when using superelastic or linear-elastic nickel-titanium.

The struts forming the proximal struts can be made from the same or a different material than the distal struts. In this manner, more or less flexibility for the proximal struts can be obtained. When a different material is utilized for the struts of

58. (Withdrawn) The cage of claim 54, further including another circumferential member attached to and located between the proximal circumferential member and the distal circumferential member.

59. (Previously Presented) The filtering device of claim 56, wherein the proximal and distal circumferential members are attached to each other by at least one connecting strut.

60. (Previously Presented) The filtering device of claim 56, further including a plurality of connecting struts which connect the proximal circumferential member to the distal circumferential member.

61. (Previously Presented) The filtering device of claim 60, wherein each connecting member is attached at a bending region on each of the proximal and distal circumferential member.

62-70. (Canceled)

71. (Previously Presented) An embolic filtering device used to capture embolic debris in a body vessel, comprising:

a guide wire having a proximal end and a distal end; and

an expandable filter assembly rotatably attached to the distal end of the guide wire, the filter assembly including a self-expanding cage having a proximal circumferential member having a plurality of bending regions formed therein, a distal circumferential member having a plurality of bending regions formed therein, the proximal circumferential member being connected to the distal circumferential member, and a filter element attached to the self-expanding cage, wherein the bending regions of the proximal circumferential member are in phase with the bending regions of the distal circumferential member.



**UNITED STATES PATENT AND TRADEMARK OFFICE  
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Page 1 of 2

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APPLICATION NO.: 10/027,915

ISSUE DATE : July 10, 2007

INVENTOR(S) : William J. Boyle et al.

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MAILING ADDRESS OF SENDER:

**Thomas H. Majcher  
Fulwider Patton LLP  
6060 Center Drive, 10<sup>th</sup> Floor  
Los Angeles, CA 90045**

This collection of information is required by 37 CFR 1.322 and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing the burden, should be sent to the Chief of Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450 Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORM TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450**

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